



provisionally rejected under the doctrine of obviousness-type double patenting over the allowed claims in the parent application (USSN 08/691,090) in view of the Wan *et al.* patent. Finally, the claims were rejected under 35 USC §112, second paragraph, for allegedly being indefinite. Each of the rejections will be addressed in the order in which they were raised.

Rejection under 35 USC § 103(a)

The Examiner has rejected claims 1-17 as allegedly being obvious over Wan *et al.*, which allegedly teaches the first four steps of the claimed methods, in view of Ogawa *et al.*, which allegedly teaches purification of DNA using anion exchange chromatography and ultrafiltration. Applicants note with appreciation that claims 17-19 are indicated as allowable over this combination because the prior art does not teach the additional step of ultrafiltration in the presence of a gel layer. In light of the basis for this decision, applicants believe the relevant claims are claims 18-20, all of which include a limitation relating to ultrafiltration in the presence of a gel layer.

The rejection of claims 1-17 is respectfully traversed. It is well settled that a *prima facie* case of obviousness requires that the combination of the cited art, taken with general knowledge in the field, must provide ***all of the elements of the claimed invention***. Moreover, to support an obviousness rejection, the cited references must provide motivation to make the claimed invention and provide a reasonable expectation of success. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991), citing *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Applicants explain below, that the Examiner has failed to make his *prima facie* case because the Examiner has failed to show that the cited references teach all of the elements of the claimed invention. Moreover, the Examiner has failed to show what would motivate one of skill to combine the teachings of the prior art, as suggested in the Office Action.

As noted by the Examiner, Wan *et al.* teaches the use of static mixers in methods of preparing nucleic acids, but fails to disclose a subsequent centrifugation step, or the use of anion exchange chromatography, to purify the nucleic acids further. The Examiner cites Ogawa *et al.* for teaching anion exchange chromatography. Applicants respectfully submit that, in fact Ogawa *et al.* provides no such teaching, but instead teaches use of ultrafiltration. Thus, the step lacking from Wan *et al.* is not provided by the Ogawa *et al.* reference. Applicants note that the only claims adding the step of ultrafiltration (claims 18-20) have been



indicated as allowable over this combination, because Ogawa *et al.* do not teach use of ultrafiltration in the presence of a gel layer.

Assuming, for the sake of argument, that the Examiner does cite a reference that teaches the use of anion exchange chromatography for the purification of nucleic acids, the Examiner must show what in the art would motivate one of skill to combine this method step with the remaining steps of the claimed method. In the absence of such a showing, the rejection would be improper.

Obviousness-Type Double Patenting

Applicants note the provisional rejection of the claims for allegedly being obvious over the allowed claims of the parent application (USSN 08/691,090) in view of the Wan *et al.* patent. Applicants will provide an appropriate Terminal Disclaimer, if necessary, when the claims are indicated as otherwise allowable.

Rejection under 35 USC § 112, second paragraph

The claims were rejected for allegedly being indefinite because step (f) of claim 1 refers to neutralization of a precipitate and the clarified solution. The claim has been amended to recite that either the "precipitation mixture", referred to in step (d) or the clarified solution can be neutralized. Support for the step of neutralizing either the precipitation mixture or the clarified solution is found at page 8, lines 24 to 27. Applicants respectfully submit that this amendment addresses the Examiner's concern.

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### CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,



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